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Office of Regulatory Policy
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 51, Rm. 6222
Silver Spring, MD 20993-0002

Attention: Beverly Friedman

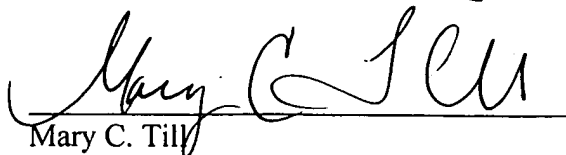
The attached application for patent term extension of U.S. Patent No. 6,835,809 was filed on October 15, 2008, under 35 U.S.C. § 156.

The assistance of your Office is requested in confirming that the product identified in the application, Nplate™ (romiplostim), has been subject to a regulatory review period within the meaning of 35 U.S.C. § 156(g) before its first commercial marketing or use and that the application for patent term extension was timely filed within the sixty-day period beginning on the date the product was approved.¹ Since a determination has not been made whether the patent in question claims a product which has been subject to the Public Health Service Act, or a method of manufacturing or use of such a product, this communication is NOT to be considered as notice which may be made in the future pursuant to 35 U.S.C. § 156(d)(2)(A).

Our review of the application to date indicates that the subject patent would be eligible for extension of the patent term under 35 U.S.C. § 156.

¹The filing of the application on October 15, 2008, was timely, given the BLA approval date of August 22, 2008. Applicant, however, misidentified at section 5 on page 2 of the application the last day the application may be submitted as October 21, 2008, pursuant to 37 C.F.R. § 1.740(a)(5). Under both 35 U.S.C. § 156(d)(1) and 37 C.F.R. § 1.720(f), a PTE applicant has sixty days to submit a PTE application, with the first day of that sixty-day period beginning on the FDA approval date. The absolute deadline for filing the present PTE Application was thus October 20, 2008, or sixty days from August 22, 2008, starting the count of the sixty-day period on August 22, 2008. The Federal Circuit in *Unimed, Inc. v. Quigg*, 12 USPQ2d 1644, 1646, made clear that "section 156(d)(1) admits of no other meaning than that the sixty-day period begins on the FDA approval date."

Inquiries regarding this communication should be directed to Raul Tamayo at (571) 272-7728 (telephone) or (571) 273-7728 (facsimile).

A handwritten signature in cursive script, appearing to read "Mary C. Tilly", is written over a horizontal line.

Mary C. Tilly

Legal Advisor

Office of Patent Legal Administration

Office of the Deputy Commissioner

for Patent Examination Policy

cc: Joseph A. Williams, Jr.
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